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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/328,975	06/09/1999	JOHN A. WOLFF	MIRUS009	7574
7590	09/09/2004		EXAMINER	
MARK K JOHNSON P O BOX 510644 NEW BERLIN, WI 531310644			SCHNIZER, RICHARD A	
		ART UNIT	PAPER NUMBER	
		1635		

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.	09/328,975	Applicant(s)	WOLFF ET AL.
Examiner	Richard Schnizer, Ph. D	Art Unit	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 07 June 2004.  
2a) This action is **FINAL**.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1,3-8,10,12-14 and 19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 1,3-8,10,12,14 and 19 is/are rejected.  
7) Claim(s) 13 is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 09 June 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/11/03.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/04 has been entered.

The declaration under 37 CFR 1.131 of Vladimir Trubetskoy was received and entered on 6/7/04.

Claims 1, 3-8, 10, 12-14, and 19 remain pending and are under consideration in this Office Action.

### ***Rejections Withdrawn***

The rejection of claims 8, 10, 12, and 14, under 35 U.S.C. 102(e) as being anticipated by Wolff et al (US Patent 6,339,067, filed 12/30/97) is withdrawn in view of the declaration under 37 CFR 1.131 of Vladimir Trubetskoy.

The rejection of claims 8, 10, and 12-14 is withdrawn in view of Applicant's amendments deleting the new matter.

***Claim Objections***

Claim 8 is objected to as ungrammatical. The word “that” in item ‘c’ should be replaced by the word “than”.

Claim 10 is ungrammatical. It lacks an article preceding the word “group”.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-7 are indefinite because they recite “the complex” in steps c) and d) without proper antecedent basis. Different antecedents for “the complex” are recited in steps a) and b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 5, 7, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (US Patent 5,908,777).

Lee teaches methods for delivering a nucleic acid complex to cells in a mammal, in which complexes are formed between polycations and nucleic acids. Subsequently new, negatively charged, complexes are formed comprising anionic lipids. See abstract. Lee also teaches that a negatively charged targeting ligand may be added to the complex, wherein the targeting ligand associates with the polycation by charge interaction. See e.g. paragraph 20, reproduced in part below.

In a preferred embodiment, an amphipathic helical oligopeptide is incorporated via charge interaction, to serve as a fusogenic peptide. Particularly preferred in this regard is a 20 amino-acid oligopeptide having the sequence GLFGAIAGFIESILELALEL (SEQ ID NO:1), where the underscored amino acids are negatively charged. ... The negative charge of the glutamic acid residues allows for charge-based interaction with the DNA/polycation complex.

The amount of ligand added is sufficient that the complex remains negatively charged, so Lee anticipates the claims.

Claims 1, 3, 4, 5, 7, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (WO 97/00965, published 1/9/97).

Lee teaches methods for delivering a nucleic acid complex to cells in a mammal, in which complexes are formed between polycations and nucleic acids. Subsequently new, negatively charged, complexes are formed comprising anionic lipids. See abstract. Lee also teaches that a negatively charged targeting ligand may be added to

the complex, wherein the targeting ligand associates with the polycation by charge interaction. See paragraphs bridging pages 12 and 13 which provides the same disclosure as paragraph 20 of US Patent 5,907,777, above.

***Response to Arguments***

Applicant's arguments filed 6/7/04 have been fully considered but they are unpersuasive.

Applicant's arguments are directed to the previous ground of rejection which depended on a different portion of the Lee disclosure than currently relied upon. The amended claims, requiring a net negative charged complex are anticipated by a different embodiment of Lee, as discussed above.

Claims 8, 10, 12, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Baker et al (Gene Therapy 4:773-782, 7/31/97).

Baker taught the formation of ternary complexes for delivering nucleic acids comprising PEI, plasmid DNA, and adenovirus. First a complex was formed between PEI and DNA, and then adenovirus was bound to the PEI through charge interactions between PEI and negatively charged regions of the adenoviral hexon protein. See abstract. Thus Baker anticipates the claims. In this rejection, the hexon protein of adenovirus is considered to be a polyanionic polymer, that is a hydrophilic, negatively charged protein.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US Patent 5,908,777) in view of the 1992 Sigma Chemical Company Catalog.

Lee taught ternary complexes between polylysine, a nucleic acid, and polyglutamic acid. See abstract, and paragraph 12 of the detailed description.

Lee was silent as to the number of monomers in the polyglutamic acid polymer.

The Sigma Chemical Company Catalog lists polyglutamic acid products in three different molecular weight ranges, the lowest of which is 2000-15000. Assuming a residue molecular weight of 128.1 for glutamic acid, an 80-residue polymer would have a molecular weight of 10248 Da. So, the three products listed by Sigma all comprise polyglutamic acid molecules in excess of 80 monomers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a polyglutamic acid with greater than 80 monomers because such polymers were readily available from Sigma Chemical Company, a general supplier of research chemicals. No polyglutamic acid preparations lacking polymers of greater than 80 monomers were available from this source.

Thus the invention as a whole was *prima facie* obvious.

**Conclusion**

No claim is allowed. Claim 13 is objected to as depending from a rejected claim, but would be allowable if rewritten in independent form with all of the limitations of the parent claim.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN  
PRIMARY EXAMINER

